

REMARKS

Reconsideration of the subject application in view of the preceding amendments and the following remarks is respectfully requested.

Claims 33-36, 38-42 and 45-48 and 50-54 are now pending in this application. In this amendment, Claims 51-54 have been added and Claim 33 has been amended to point out with greater specificity subject matter believed to be inherently included within the claims and/or correct formal deficiencies which the Examiner has brought to the Applicants' attention. No new matter has been added to the subject application by this amendment, nor have any new issues been raised.

The Office Action

In the outstanding Office Action, Claims 33-36, 38-42, 45-48 and 50 were rejected for formal reasons under 35 U.S.C. §112, second paragraph. The Examiner indicated that the request for continued examination has been entered and the finality of the previous Office Action dated January 29, 2003 has been withdrawn. The Examiner also indicated that the information disclosure statement filed on December 26, 2002 is now in compliance with 37 CFR 1.97 and being considered by the Examiner.

Response by Applicant

Applicants' respectfully traverse the Examiner's rejections primarily because of the reasons set forth herein below.

With respect to the outstanding Office Action, on Page 4, the Examiner states:

The reply filed on 07/03/03 is not fully responsive to the prior Office Action because of the following omissions or matters: it is noted that the Office Action dated 01/29/03 indicated that the application is in condition for allowance based on the preamble of claim 33. It appears that applicant inadvertently deleted the Markush group of surfactant, which was previously recited in claim 33. See 37 CFR 1.111. Accordingly, this application is in condition for allowance if the 112, 2nd paragraph is resolved, and the Markush group of surfactant is incorporated into claim 33.

Applicants' respectfully disagree with the Examiner's assertion that Applicants' reply of July 7, 2003 was not fully responsive to the Office Action dated January 29, 2003. In support thereof, Applicants point out that on Page 5 of the January 29th Office Action, the Examiner states that the instant application "would be in the condition for allowance if amend the claims to use the format suggested in the Interview Summary dated 01/23/03 and 01/27/03." In this Interview Summary, the Examiner stated that "to place the application in condition for allowance, it was suggested to amend the claims language so that they would read similar to the claims of the Parikh patent (id), and file a terminal disclaimer regarding to the subject matter in the Parikh 5922355."

As shown by the written record of the instant case, the Examiner neither stated nor suggested that a Markush group must be incorporated into Claim 33 of the instant application for the claim to be allowable. Applicants point out that the Examiner

suggested to amend claims to "read similar to the Parikh patent," and Applicants note that in the Parikh patent referred to by the Examiner (*i.e.*, U.S. Patent No. 5,922,355, hereinafter referred to as the "Parikh '355 patent"), none of the independent claims contain Markush groups. Applicants' believe their reply of July 3, 2003 amended Claim 33 so that Claim 33, other than the specific recitation of fenofibrate, read similar to the claims of the Parikh '355 patent. Furthermore, by filing a terminal disclaimer along with the July 3rd reply, Applicants' believed the case was put in condition for allowance according to the Examiner's comments in the documents of record (*i.e.*, the January 29th Office Action and Interview Summary).

Thus, Applicants' reply filed on July 3, 2003 was believed to be fully responsive to the Examiner's action dated January 29, 2003 because, among other things, Applicants' reply pointed out the errors in the examiner's action, replied to every ground of objection and rejection in the prior office action, and presented arguments pointing out the specific distinctions believed to render the claims patentable over any applied references, as required by 37 CFR 1.111(b).

Turning now the outstanding office action, no rejections based on prior art have been asserted against the instant application. Thus, Applicants' believe that the claims as now presented, which have been amended to remove the formal deficiencies cited by the Examiner in the outstanding Office Action, are now clearly in condition for allowance. It is respectfully submitted that claims as now presented are directed to subject matter which is neither disclosed nor suggested by any references in the relevant art, alone or combined, and the instant application is in condition for allowance.

Specifically, a "method of preparing fenofibrate microparticles, including a particle size reduction process for reducing the initial average particle size, the method comprising the steps of: (1) mixing the fenofibrate particles with (a) a natural or synthetic phospholipid and (b) at least one non-ionic, anionic or cationic surfactant, prior to or during the particle size reduction process, and thereafter (2) applying energy to the mixture sufficient to produce fenofibrate microparticles having a volume-weighted mean particle size value that is about 50% smaller than particles produced without the presence of the surfactant using the same energy input," as now recited in amended Claim 33, is neither disclosed nor suggested by the relevant art.

In addition, a "method of preparing fenofibrate microparticles which includes reducing the initial average particle size by sonication, homogenization, milling, microfluidization, recrystallization, and precipitation, or a combination thereof, the method comprising the steps of: (1) mixing the fenofibrate particles with (a) a natural or synthetic phospholipid and (b) at least one non-ionic, anionic or cationic surfactant, prior to or as the initial average particle size is reduced; and (2) applying energy to the mixture sufficient to produce fenofibrate microparticles having a volume-weighted mean particle size value that is about 50% smaller than particles produced without the presence of the surfactant using the same energy input," as recited in new Claim 53, is neither disclosed nor suggested by the relevant art.

Since independent claims 33 and 53 contain limitations which are neither taught nor suggested by any references in the relevant art, either alone or combined with any other references, these claims are directed to subject matter which is neither anticipated or

obvious. Furthermore, since the claims that depend from independent claims 33 and 53 provide further limitations thereto, the dependent claims 34-36, 38-42 and 45-48, 50-52 and 54 are also not anticipated or obvious by the relevant art, either alone or combined with any other references.

In addition, in consideration of the previously filed terminal disclaimer, Applicants' believe there remains no further impedance to issuance of the instant application with claims as amended herein. Thus, it is respectfully submitted that as a result of this amendment and discussion relating thereto, all of the claims presently pending in this application are in condition for allowance, and such action is earnestly solicited.

Page 2 of the outstanding Office Action incorrectly indicates that the information disclosure statement was filed on December 26, 2003, however, the information disclosure statement was actually filed on December 26, 2002. Also on Page 2, the Examiner indicates that the information disclosure statement is in compliance with the provisions of 36 CFR 1.97, and is "being considered by the examiner" Once again, Applicants' respectfully request that the Examiner clarify her position with regard to whether the references cited in this information disclosure statement have been considered.

If the Examiner believes that a personal or telephonic interview may facilitate resolution of any remaining matters, Applicant's representative may be contacted at the number indicated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard Newman", with a long horizontal flourish extending to the right.

Richard H. Newman, Reg. No. 41,222
Edwards & Angell, LLP
Three Stamford Plaza
301 Tresser Blvd., 6th Floor
Stamford, CT 06901
Tel. No. (203) 353-6836

Date: January 1, 2004